DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

AXON Medical Technologies Corp.
% Mr. Chas Yu
Quality Assurance Manager
18 Tanager Avenue, Suite 303
Toronto, Ontario M4G 3R1
CANADA

March 6, 2015

Re: K141536
Trade/Device Name: Viewing Client Mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 19, 2015
Received: March 2, 2015

Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141536

Device Name
Viewing Client Mobile

Indications for Use *(Describe)*
The Viewing Client Mobile is a software application that is intended to be used by qualified medical professionals for the review of medical images derived from multiple modalities. Clinical reports can also be viewed using this device.

The Viewing Client Mobile application can be used to perform image manipulation (for example, window width and level, zoom, pan, rotation) and measurement. It can display both lossless and lossy compressed images. For lossy images, the user must determine if the level of loss is acceptable for their purposes.

The Viewing Client Mobile application provides wireless and portable access to medical images from only the following modalities: MRI, CT, X-ray and Ultrasound. It is not intended to replace a full workstation and should be used only when there is no access to one.

The Viewing Client Mobile application must not be used for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

5 510(k) Summary [21 CFR 807.92(c)]

5.1 General Information

5.1.1 Manufacturer Information

AXON Medical Technologies Corp.
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Toronto, Ontario
Canada M4G 3R1
Email: peter.bak@axonmed.com
Tel: (416) 421-2588
Fax: (416) 421-5603

5.1.2 FDA Registration No.

Pending Approval of first 510(k) submission.

5.1.3 Submitter Information

Chas Yu
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Email: chas.yu@axonmed.com

Date Summary Prepared: March 31st, 2014

5.1.4 Device Information

Trade Name: Viewing Client Mobile
Common Name: Medical Image Processing Software
Classification Name: Picture Archiving and Communication System (PACS), (21 CFR Part 892.2050, Product Code LLZ)

5.1.5 Predicate Devices

K112930	MobileMIM	MIM Software Inc. (formerly MIMvista Corp.)

5.2 Device Description

AXON Medical Technology Corp.'s Viewing Client Mobile is a viewer that facilitates the secure viewing of 2D, DICOM 3.0-compliant soft-copy imaging studies both within and without the Enterprise context. The product operates through an API.

Viewing Client Mobile is used under mobile viewing conditions within the device's intended use. Viewing Client Mobile app runs on iOS platforms.

Core measurement and image manipulation tools provided by the Viewing Client Mobile include zoom, pan, invert, W/L, Pixel Value/ Line/ Angle, ROI and CINE. The Viewing Client Mobile also supports multi-series and study display.

The Viewing Client Mobile app operates on the iPad, a portable, "off-the-shelf" hardware device, used to wirelessly access medical images under mobile conditions, and is therefore more sensitive to factors not typical for reading room workstations (e.g. display condition, variable lighting, viewing angle, etc.). The user is therefore instructed to properly follow the operating instructions provided with the hardware device, utilize the Viewing Client Mobile's risk mitigation features and heed precautions related to safe device use.

5.3 Intended Use/ Indications for Use

The Viewing Client Mobile is a software application that is intended to be used by qualified medical professionals for the review of medical images derived from multiple modalities. Clinical reports can also be viewed using this device.

The Viewing Client Mobile application can be used to perform image manipulation (for example, window width and level, zoom, pan, rotation) and measurement. It can display both lossless and lossy compressed images. For lossy images, the user must determine if the level of loss is acceptable for their purposes.

The Viewing Client Mobile application provides wireless and portable access to medical images from only the following modalities: MRI, CT, X-ray and Ultrasound. It is not intended to replace a full workstation and should be used only when there is no access to one.

The Viewing Client Mobile application must not be used for the primary interpretation of mammographic images.

5.4 Technological Characteristics Comparison Table

Point of Comparison	Viewing Client Mobile	Mobile MIM
510(k) Number	-	K112930
Intended Use / Indications for Use	The Viewing Client Mobile is a software application that is intended to be used by qualified medical professionals for the review of medical images derived from multiple modalities. Clinical reports can also be viewed using this device. The Viewing Client Mobile application can be used to perform image manipulation (for example, window width and level, zoom, pan, rotation) and measurement. It can display both lossless and lossy compressed images. For lossy images, the user must determine if the level of loss is acceptable for their purposes. The Viewing Client Mobile application provides wireless and portable access to medical images from only the following modalities: MRI, CT, X-ray and Ultrasound. It is not intended to replace a full workstation and should be used only when there is no access to one. The Viewing Client Mobile application must not be used for the primary interpretation of mammographic images.	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, MRI, X-Ray and Ultrasound. Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans. Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.
Receive, Store, Display, and Process Digital Medical Images	Yes	Yes

Display of Clinical Patient Data when no access to a workstation	Yes	Yes
Image Fusion	No	Yes
Multiplanar reconstruction (MPR)	No	Yes
Maximum Intensity Projection (MIP)	No	Yes
Standardized Uptake Value (SUV)	No	Yes
Distant Measurements	Yes	Yes
Window/ Level	Yes	Yes
Zoom/ Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	MRI, CT, X-Ray and Ultrasound	SPECT, PET, CT, MRI, X-Ray, Ultrasound
Remote Handheld Viewing Device	Yes	Yes
Operating Platform	Apple iOS	Apple iOS
Hardware Requirements	iPad 3 and 4 (Apple iOS handheld devices)	Apple iOS Handheld Devices
Installation Requirements	Downloadable as app	Downloadable as app
Logging of Audit Trails	Yes	No
Ambient Light Display	Yes	Yes

Verification Tool		
Support for radiation treatment plans	No	Yes

5.5 Performance Testing

Bench Testing was performed on all supported off-the-shelf mobile platforms to confirm the Viewing Client Mobile can be calibrated to provide optimal viewing conditions for performing diagnostic reads under prescribed illuminance ranges.

The tests were performed in accordance with the test guidelines provided in AAPM Assessment of Display Performance for Medical Imaging Devices (2005). The Test plan was validated by an expert in luminance and illuminance testing and executed internally. Test equipment calibration is certified traceable to NIST. A total of seven tests were performed. In each case acceptance criteria was met.

Furthermore, AXON Medical Technologies has conducted verification, validation, and functional testing on Viewing Client Mobile software. In all cases, the software passed its performance requirements and met specifications.

5.6 Clinical Testing

An Image Quality Demonstration study was performed by certified Radiologists using a variety of modalities, specifically MRI, CT, X-ray and Ultrasound, under different environmental conditions. The radiologists conducted a side-by-side comparison of the predicate and Viewing Client Mobile to evaluate and compare the overall image quality of a series of representative patient images form the range of modalities supported by the device. All radiologists indicated that the image quality of Viewing Client Mobile was acceptable in terms of overall quality, sharpness and contrast and that it would enable diagnostic reads to be made confidently. No image artifacts were noted by the reviewers. Results of the clinical testing affirm the diagnostic image viewing capability of Viewing Client Mobile when used as indicated.

5.7 Substantial Equivalence

The predicate comparison chart in tandem with the above consideration provides evidence in support of the determination that Viewing Client Mobile is substantially equivalent to K112930 MobileMIM Software Applications.

Viewing Client Mobile provides a portable diagnostic viewer of medical images substantially equivalent to K112930 MobileMIM. AXON is of the opinion that the Viewing Client Mobile does not introduce new safety or performance risks and is safe for commercial release.